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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,396	03/24/2004	Jeffry B. Skiba	12937-011002	3326

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EXAMINER	
WOO, JULIAN W	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
10/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,396	SKIBA ET AL.	
	Examiner	Art Unit	
	Julian W. Woo	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-36 and 51-55* is/are pending in the application.

4a) Of the above claim(s) *8,10,11,14,15,19,20,25,26,30,32-36 and 51-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,9,12,16-18,21-24,27-29,31 and 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1, 3-7, 9, 12, 13, 16-18, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mollenauer et al. (5,562,685) in view of Zocher (3,645,222). Mollenauer et al. disclose the invention substantially as claimed. Mollenauer et al. disclose, at least in figures 1 and 12 and in col. 9, line 37 to col. 10, line 5; a suturing device including a handle (102 or 12), an elongated shaft (104 or 102) with a distal end and extending along an axial direction, a sharpened tip (106 or 104), and a detachable suture (110) that is a length of material; where the sharpened tip (106) includes an elongated opening (108) configured to trap a suture at a selected point and including a curved portion and configured to permit suture to pass lengthwise through the opening, where the sharpened tip (104) has a hooked configuration or is angularly bent relative to

the shaft in a selected direction, where the sharpened tip is curved at least partially about the distal end of the shaft (102) or extends at an angle and to one side of the distal end, where the sharpened tip (104) extends at least partially forward from the distal end with a concave configuration, and where the sharpened tip is angularly bent about a tip axis that is non-parallel with the axial direction (i.e., each coil portion of the needle, including the tip, is angled with respect to the axial direction) and is curved about the axial direction.

However, Mollenauer et al. do not disclose a sharpened tip including an exposed, tapered, and closed opening or an opening with at least a portion dimensioned to wedge and hold a suture, having a central portion with a tapered configuration, or comprising a tapered opening. Zocher teaches, at least in figures 1, 2, 6, and 7 and in col. 1, lines 52-57; a device with a sharpened tip including an opening (15) that is exposed, tapered, and closed; or has at least a portion dimensioned to wedge and hold a suture, having a central portion with a tapered configuration, or comprising a tapered opening. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the opening of the device of Mollenauer et al., so that it has the tapered configuration as taught by Zocher. Such an opening would enhance the trapping of a suture at a selected point, so that a user can manipulate the suture and sharpened tip with better control during suturing (i.e., the suture would less likely move inadvertently in an opening as taught by Zocher).

3. Claims 21-24, 27-29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mollenauer et al. in view of Zocher, and further in view of Yoon

(5,437,680). Mollenauer et al. in view of Zocher disclose the invention substantially as claimed, but do not that the sharpened tip with an opening or the needle with a through opening is detachable from the distal end of the elongated shaft. Yoon teaches, at least in figure 17 and in col. 9, line 65 to col. 10, line 7; a device with an elongated shaft (104) including a detachable needle (94) at the distal end of the shaft and holding a suture. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Yoon, to modify the device of Mollenauer et al. in view of Zocher, so that the sharpened tip with an opening or the needle with a through opening is detachable from the distal end of the elongated shaft. A needle with a suture detached from the elongated shaft would allow a surgeon to manipulate the needle itself for stitching of tissue without any physical interference from the elongated shaft. Also, the elongated shaft would be capable of receiving new or replacement needles.

Response to Amendment

4. The rejection of claims under 35 U.S.C. 112, 2nd paragraph, is hereby withdrawn.

Applicant's arguments regarding the rejection of claims based on the Mollenauer and Zocher references have been fully considered but they are not fully persuasive: See the new and restated grounds of rejection above. Firstly, Mollenauer indeed discloses a tip axis that is non-parallel (i.e. perpendicular) with the axial direction defined by the shaft. That is, the "spiral" extends along and parallel with the axial direction, while each coil portion (including the tip) is angled or slanted relative to the axial direction. Secondly, Zocher indeed teaches a needle eye or an opening as claimed. The teaching regarding a slot in a needle is not germane to the teaching regarding the opening, so

the slot teaching was not applied in modifying the device of Mollenauer. Finally, Zocher's needle eye is indeed designed with a central portion having a tapered configuration. That is, the central portion of the eye has a wide width that immediately tapers, such that an end of the opening has a narrow width.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Julian W. Woo
Primary Examiner

October 3, 2007